



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG - 2 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

11 60 '00 AUG -7 10:38

Michael R. Ronayne  
Director of Regulatory Affairs  
Accelerated Care Plus, LLC  
6700 SW Topeka Blvd.  
Forbes Field, Bldg. 140  
Topeka, Kansas 66619

Re: Docket No. 00P-1295  
Neuromuscular Electrical Stimulators

Dear Mr. Ronayne:

This responds to your citizen petition, dated May 2, 2000, requesting a variance from the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) for patient cables used with your firm's Omnistim 500, Omnistim FX2, and Neuroprobe 500 neuromuscular electrical stimulators. I apologize for our delay in responding.

The rationale for your request is that your firm has experienced delays in obtaining adequate quantities of suitable adapters for distribution to users of these devices. You requested a variance on behalf of your customers to allow clinicians to continue using their existing cables already in their possession for up to 90 days beyond the effective date of the performance standard. Your petition does not request any variance for continued manufacturing or distribution of non-compliant cables.

I am granting your petition. User facilities may continue to use their existing non-compliant lead wires with the referenced neuromuscular electrical stimulators until August 7, 2000, by which time they should have received adapters and replacement cables that are compliant with the performance standard.

I trust that this response fully addresses your concerns. If additional information is required, please contact Stewart Crumpler in our Office of Compliance at (301) 594-4659.

Sincerely yours,

Linda S. Kahan  
Deputy Director for Regulations and Policy  
Center for Devices and Radiological Health

00P-1295

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